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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,545	04/15/2005	Adam Siddiqui-Jain	532232000900	3896

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	PAPER NUMBER
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

TJ

Office Action Summary	Application No.	Applicant(s)	
	10/531,545	SIDDIQUI-JAIN, ADAM	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 7-12* is/are rejected.

7)☒ Claim(s) *5 and 6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to Comply*.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, the retrovirus being HIV and the quadruplex structure being an intermolecular structure in the reply filed on November 13, 2006 is acknowledged. The traversal is on the ground(s) that the election with regard to HIV and an intermolecular structure should be a species election and not a subgroup/species election. This is not found persuasive because as indicated on pages 3 and 4 of the previous Office action a species election requirement exists among "A. The species of retrovirus are as follows:" and "B. The quadruplex are as follows:" if Group I is elected. There is no indication that a subgroup/species election exists, merely a species election among two distinct species listings (i.e. A. and B.). However, given the additional argument about the relatedness of the retroviruses of claim 2 and due to the amendments made to claims 9 and 10 the species election requirements are withdrawn.

The election requirement with regards to inventions I, II and III is still deemed proper and is therefore made FINAL.

Claims 13-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 13, 2006.

Claims 1-12 are examined in this Office action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on August 8, 2005 was filed. submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Objections

Claims and Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Claims 4-6 are objected to because claims 4-6 do not contain specific SEQ ID NO:s. In addition, pages 2, 7, 17 and 18 of the specification contain nucleic acid sequences without proper SEQ ID NO:s.

Applicants must comply with sequence rules in order to be considered a complete response to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zennou et al. (Cell, 2000), Haseltine et al. (US 5,759,768), Hotoda et al. (Journal of Medicinal Chemistry, 1998), Sundquist et al. (Proceedings of the National Academy of Science USA, 1993) and Charneau et al. (US 6,682,907 B1).

The instant invention is drawn to a method of identifying an antiviral candidate molecule that binds with a quadruplex structure within a central flap nucleic acid sequence of a retrovirus, such as HIV. The quadruplex structure is an intermolecular parallel structure formed by a dimmer of two intramolecular hairpin structures. The binding of the candidate molecule with the central flap sequence is detected by circular dichroism (CD). The nucleic acid sequence comprises the nucleotide sequence of TTGGGGGGTA.

Haseltine et al. teach methods of identifying factors that affect the integration of a DNA sequence into a target DNA sequence. Preferably, viral integration into a target sequence, such as the genome of HIV-1, HIV-2, or SIV. However, Haseltine et al. do not teach identifying candidate antiviral molecules that bind to the central flap quadruplex structure, the use of potassium ions, the use of CD or an intermolecular quadruplex structure.

Zennou et al. teach the involvement of the central DNA flap of HIV-1 with regard to the importing of its genome into the nucleus of a host cell and subsequent integration. Zennou et al. observed that mutants devoid of the central DNA flap were not able to traffic into the nucleus, even though there was localization near the nuclear pores. Zennou et al. discuss the implications of mutations involving the central DNA flap resulting in a marked decrease of viral DNA integration into the genome of the host cell, an essential event in HIV infections.

Hotoda et al. teach the screening for an anti-HIV-1 oligomer conjugate. Hotoda et al. tested multiple 15-mers complementary to different sites of HIV-1 RNA resulting in one active compound specific to the *tat* region of HIV-1. The findings of Hotoda et al. revealed that an aromatic group at the 5' end of the 15-mer greatly increased its anti-viral properties by interfering with the viral adsorption and cell fusion. Hotoda et al. utilized CD to analyze the candidate, a common method of analyzing proteins and nucleic acids.

Sundquist et al. observed the stable formation of guanine hairpin dimer structures of an antiparallel helix within the genome of HIV. Sundquist discuss the importance of potassium ions presence to the stability of these intermolecular structures.

Charneau et al. disclose a HIV DNA sequence comprising the claimed nucleic acid of the instant invention as SEQ ID NO:33.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Haseltine et al. in order to detect an antiviral molecule capable of binding to a quadruplex structure of a central flap of a retrovirus, thereby inhibiting viral activity. One would have been motivated to do so, given the suggestion by Haseltine et al. that the method be used to screen for agents that affect the integration of foreign DNA into target DNA. There would have been a reasonable expectation of success, given the knowledge that the central DNA flap of HIV is necessary for trafficking of its genome into the nucleus of a host cell in order for genomic integration to take place, as taught by Zennou et al. and that said nucleic acid would comprise SEQ ID NO:33 of Charneau et al., also given the knowledge that screening for potential anti-HIV compounds can be analyzed by CD, as taught by Hotoda et al., and also given the knowledge that regions of the HIV genome are capable of forming into intermolecular dimers of

hairpin structures that are stabilized by potassium ions, as taught by Sundquist et al. Thus the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Summary

Claims 5 and 6 are allowable, pending amendments to the claims (see Objections above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Benjamin Blumel
Patent Examiner

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice to Comply	Application No. 10/531,545	Applicant(s) Siddiqui-Jain, Adam
	Examiner Benjamin Blumel	Art Unit 1648

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☐ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The specification and claims 4-6 lack the necessary nucleic acid SEQ ID NO:s, see Office action.

Applicant Must Provide:

☐ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☐ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application.**

☐ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
For CRF Submission Help, call (703) 308-4212 or 308-2923
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